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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/655,911

09/05/2003

Arturo J. Angel

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MORRISON & FOERSTER LLP

755 PAGE MILL RD

PALO ALTO, CA 94304-1018

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

03/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/655,911	Applicant(s) ANGEL ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-6-07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-44 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 14-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-6-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of response, amendment and IDS all dated 12-6-07 is acknowledged.

Response to Arguments

1. Applicant's arguments, see pages 1-3, filed 12-6-07, with respect to the rejection(s) of claim(s) Claims 1, 3-4, and 10-13 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. 5,910,512 to Conant (Conant) in view of Wholehealthmd (cited in the Office Action dated June 15, 2003) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,962,532 to Campbell in view of Wholehealthmd (cited previously) and .
4. Campbell teaches methods and compositions for treating pain at a specific site with an effective amount of capsaicin. Campbell teaches that while capsaicin is effective in pain treatment, the side effects of capsaicin include activation of nociceptors in peripheral tissues desensitization of peripheral nociceptors, cellular degeneration of sensitive A-fiber and C-fiber etc (col. 1, col. 3-4). In order to overcome the above effects, Campbell teaches that anesthesia is first provided to the site of where capsaicin

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needs to be administered, followed by administration of capsaicin (summary of invention). Additionally, Campbell states that any irritant effect of capsaicin is relieved by administering a narcotic analgesic (see claim 9 of Campbell).

5. Wholehealthmd teaches a capsaicin product for relieving pain and arthritis. The reference suggests that capsaicin causes stinging and burning sensation, and suggests washing the hands thoroughly after applying the cream, with soapy water (page 3, special concerns).

6. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention that the irritant side effect caused by administering capsaicin in the teachings of Campbell can be overcome either by administering a narcotic analgesic or by washing of the site where capsaicin has been injected with a soap composition that can successfully remove capsaicin because Wholehealthmd suggests capsaicin causes allergy in some people and has to be washed off to avoid any burning sensation to the eyes or other sensitive body parts. While neither references teach a kit and a separately packaged second composition with the claimed solubility of capsaicin in the second composition, it would have been obvious for a skilled artisan to first apply capsaicin for its intended pharmacological effect and then apply a soap solution to remove the irritant effect so as to allow the effect of capsaicin be achieved. Further, the soapy solution intended to remove the irritant effect of capsaicin should have to be solubilizing capsaicin so as to successfully remove the irritant effect. Campbell teaches the amount of capsaicin that is effective for pain relief and is within the claimed range (see claims of Campbell).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
February 29, 2008